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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,795

11/13/2003

Rosanne Crooke

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EXAMINER

EPPS FORD, JANET L

ART UNIT

PAPER NUMBER

1633

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
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3 MONTHS

04/09/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

## Office Action Summary

Application No.

10/712,795

Applicant(s)

CROOKE ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 109-145 and 197-215 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 125-145 and 197-215 is/are allowed.
- 6) ☒ Claim(s) 109-116 is/are rejected.
- 7) ☒ Claim(s) 117-124 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 109-145, 197-215 are presently pending.

***Response to Amendment/Arguments***

***Claim Rejections - 35 USC § 112***

2. The rejection of claims 109-124 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to Applicant's amendment.
3. The rejection of claims 142-145 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment.

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 142-145 under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (US Patent No. 6172216, Published January 9, 2001), is withdrawn in response to Applicant's amendment to the claims.

***Double Patenting***

5. The rejection of claims 109-145 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/920,612, is withdrawn in response to Applicant's amendment to the claims in the copending application.

***New Grounds of rejection***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 109-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Jarvis et al. (WO 98/32846 A2).

Jarvis et al. disclose a nucleotide sequence of 14 base pairs in length (See SEQ ID NO: 347, page 53) that hybridizes to at least 8 contiguous nucleobases of nucleotides 3249-3268 of SEQ ID NO: 3 of the instant application. This nucleotide sequence comprises no more than two mismatches within nucleotides 3249-3268 of SEQ ID NO: 3. The phrase "antisense compound" or "antisense oligonucleotide" set forth in the instant claims is interpreted as an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, although the nucleotide sequence structure disclosed in Jarvis et al. is silent in regards to its use as an antisense compound, absent evidence to the contrary, the prior art nucleotide sequence meets all the structural requirements of the instant claim, and thus anticipates the claimed invention.

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 109-114 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Kazemi et al. (WO 200226768 A2).

Kazemi et al. discloses an allele specific oligonucleotide of 15 nucleobases in length, having the following sequence:

AGGCTCAGTCTGCGY (SEQ ID NO: 46);<sup>1</sup> Y is T or C, and said oligonucleotide hybridizes to at least 8 contiguous nucleobases of nucleotides 3249-3268 of SEQ ID NO: 3 of the instant application. This compound comprises a single mismatch within nucleotides 3249-3268 of SEQ ID NO: 3. The phrase “antisense compound” or “antisense oligonucleotide” set forth in the instant claims is interpreted as an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, although the nucleotide sequence structure disclosed in Kazemi et al. is silent in regards to its use as an antisense compound or oligonucleotide, absent evidence to the contrary, the

prior art nucleotide sequence meets all the structural requirements of the instant claim, and thus anticipates the claimed invention.

Additionally, Kazemi et al. teach that the oligonucleotides of their invention may include modifications, see for example the following passage from page 12 of this reference:

As used herein, the term "oligonucleotide" refers to a polynucleotide molecule having less than about 100 nucleotides. A preferred oligonucleotide of the invention is 10 to 35 nucleotides long. More preferably, the oligonucleotide is between 15 and 30, and most preferably, between 20 and 25 nucleotides in length. The exact length of the oligonucleotide will depend on many factors that are routinely considered and practiced by the skilled artisan. The oligonucleotide may be comprised of any phosphorylation state of ribonucleotides, deoxyribonucleotides, and acyclic nucleotide derivatives, and other functionally equivalent derivatives. Alternatively, oligonucleotides may have a phosphate-free backbone, which may be comprised of linkages such as carboxymethyl, acetamidate, carbamate, polyamide (peptide nucleic acid (PNA)) and the like (Varma, R. in Molecular Biology and Biotechnology, A Comprehensive Desk Reference, Ed. R. Meyers, VCH Publishers, Inc. (1995), pages 617-620). Oligonucleotides of the invention may be prepared by chemical synthesis using any suitable methodology known in the art, or may be derived from a biological sample, for example, by restriction digestion. The oligonucleotides may be labeled, according to any technique known in the art, including use of radiolabels, fluorescent labels, enzymatic labels, proteins, haptens, antibodies, sequence tags and the like.

Thus, the oligonucleotides of Kazemi et al. may comprise phosphate modifications, nucleotide derivatives, and may also comprise PNA modifications which comprises wherein the sugar and phosphate backbone is replaced with a polyamide backbone.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 109-116 rejected under 35 U.S.C. 103(a) as being unpatentable over Kazemi et al. in view of Dempcy et al. (US 6,949,367) and Simeonov et al.
12. The discussion of Kazemi et al. as set forth above is incorporated here. However, Kazemi et al. does not teach 2'-O-methoxyethyl or bicyclic sugar modifications.

Dempcy et al. teach the use of 2'-O-methoxyethyl modifications in oligonucleotides, wherein the modified oligonucleotides exhibit increased mismatch discrimination (col. 52, lines 2-17).

Simeonov et al. teach the use of oligonucleotide primers bearing locked nucleic acid-modifications in application of allele specific PCR. Simeonov et al. concluded that primer probes bearing LNA modifications have superior properties in the discrimination of single nucleotide variations.

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to combine the teachings of Kazemi et al., Dempcy et al. and Simeonov et al. in the making of the claimed invention. One of ordinary skill in the art would have been motivated to make this modification since the oligonucleotides of Kazemi et al. are disclosed as useful in the identification of specific alleles in a target nucleic acid, and the modifications of Dempcy et al. and Simeonov et al. are specifically disclosed as useful for increasing the properties of modified oligonucleotides for discrimination of nucleotide variations.

***Claim Objections***

13. Claims 117-124 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

14. Claims 125-145, and 197-215 are allowable over the prior art.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

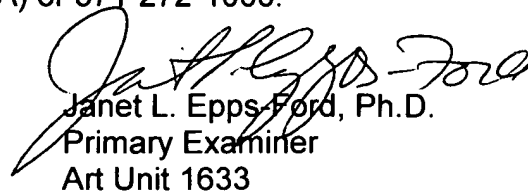
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Janet L. Epps-Ford, Ph.D.  
Primary Examiner  
Art Unit 1633

JLE